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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,605	12/31/2001	George A. O'Toole	00246-266US1	1939
26161	7590	04/07/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			FORD, VANESSA L	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/673,605

**Applicant(s)**

O'TOOLE ET AL.

**Examiner**

Vanessa L. Ford

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 1/04.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **Election/Restriction**

1. A new restriction requirement is set forth based on the preliminary amendment filed December 27, 2000 (resubmitted January 6, 2004). Claims 23, 36 and 38 have been amended. Claims 40-54 have been added. The restriction requirement mailed October 10, 2003 has been vacated. The Office apologizes for the oversight. The new restriction requirement follows:

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

### **Election/Restrictions**

Group I      Claims 1-6 and 11-21 are drawn to the special technical feature of nucleic acid molecule and 1<sup>st</sup> method of using the nucleic acid molecule. Further species election required.

Group II      Claims 7-8, 10, 22-26 and 40-46 are drawn to the special technical feature of polypeptide and 1<sup>st</sup> method of using the polypeptide. Further species election required.

Group III      Claim 9 is drawn to the special technical feature of an antibody.

Art Unit: 1645

- Group IV      Claims 27-29 are drawn the special technical feature of a method for inhibiting participation of a bacterium in formation of a biofilm on the surface comprising inhibiting the synthesis or function of a flagellum (2<sup>nd</sup> method of using the nucleic acid molecule). Further species election required.
- Group V      Claims 30-33 are drawn to the special feature of a method for inhibiting participation of a bacterium in formation of a biofilm comprising inhibiting the synthesis or function of a pilus (2<sup>nd</sup> method of using the polypeptide). Further species election required.
- Group VI      Claims 34-37 are drawn to the special feature of a method of screening for a compound that inhibits bacterial pathogenicity (3<sup>rd</sup> method of using the nucleic acid molecule).
- Group VII      Claims 38-39 and 47-50 are drawn to the special feature of a method of stimulating formation of a biofilm (4<sup>th</sup> method of using the nucleic acid molecule).
- Group VIII      claims 51-54 are drawn to the special technical feature of a method of screening using the nucleic acid. (5<sup>th</sup> method of using the nucleic acid molecule).

3. An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression special technical features that define a contribution which each of the claimed inventions, considered as a whole makes over the prior art, see MPEP 1.475 (a). There is no technical relationship required between Groups I, II and III because the Groups are structurally and functionally distinct each from the other. There is also no technical relationship required for Groups IV, V, VI, VII and VIII because the Groups are drawn to different methods which have different goals, require different method steps and parameters. If multiple products, processes of manufacture or uses are claimed, the first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and MPEP 1.476(c). Therefore, Groups IV- VIII are drawn to 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> methods of using the claimed products. The inventions listed as Groups I-VIII do not share a corresponding special technical feature under PCT Rule 13.2.

Art Unit: 1645

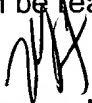
4. A. In the event applicant elects Group I, claims 1-6 and 11-21 applicant is required to elect a single sequence. Claims 1-6 and 11-21 recite distinct sequences based on structural differences and are patentably distinct one from another.
- B. In the event that applicant elects Group II, claims 7-8, 10, 22-26 and 40-46 applicant is required to elect a sequence. Claims 7-8, 10, 22-26 and 40-46 recite distinct SEQ ID Nos., based on structural differences patentably distinct one from another.
- C. In the event that applicant elects Group IV, claims 27-29 applicant is required to elect a single sequence. Claims 27-29 recite distinct SEQ ID Nos., based on structural differences patentably distinct one from another.
- D. In the event that applicant elects Group V, claims 30-33 applicant is required to elect a single sequence. Claims 30-33 recite distinct SEQ ID Nos., based on structural differences patentably distinct one from another.

Art Unit: 1645


5. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford  
Biotechnology Patent Examiner  
March 30, 2004



NITA MINNIFIELD  
PRIMARY EXAMINER  
3/31/04